510(K) Summary of Safety and Effectiveness

MAY - 6 2011

Prepared in accordance with 21 CFR Part 807.92.

Date Prepared: December 20, 2010

Submitter: GE Healthcare, (GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC doing business as GE Medical Systems Lunar)
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DEVICE INDENTIFICATION

Trade Name: GE Lunar Visceral Fat Software

Common/Usual Name: Bone Densitometer

Classification Name: Bone Densitometer
Class II, KGI, 21CFR 892.1170

DEVICE DESCRIPTION:

The Visceral Fat Software option is part of a GE Lunar DXA bone densitometer. It uses data from a DXA total body scan to estimate the visceral adipose tissue (visceral fat) mass and volume within the android region in a male or female population between the age of 18 and 90 with a BMI between 18.5 and 40.

INDICATIONS FOR USE:

The GE Lunar Visceral Fat Software option used on GE Lunar DEXA bone densitometer total body scans estimates the visceral adipose tissue (visceral fat) content within the android region in a male or female population between the age of 18 and 90 with a BMI between 18.5 and 40, excluding pregnant women. The content that is estimated is the Visceral Fat Mass and Visceral Fat Volume. The values can be displayed in user defined statistical formats and trends.

The estimated visceral fat content is useful to health care professionals in their management of diseases/conditions where the disease/condition itself, or its treatment, can affect the relative amounts of visceral fat content in the android region. The GE Lunar Visceral Fat Body Composition Software option does not diagnose disease, or recommend treatment regimens, or quantify treatment effectiveness. Only the health care professional can make these judgments. Some of the diseases/conditions for which visceral fat estimation is useful include hypertension, impaired fasting glucose, impaired glucose tolerance, diabetes mellitus, dyslipidemia, and metabolic syndrome.

TECHNOLOGY

GE Lunar Bone Densitometers use a technique called Dual-energy X-ray Absorptiometry or DXA. DXA measures the attenuation of an x-ray beam comprised of two energy levels after passing the beam through the body of a subject. When the dual-energy x-ray beam passes through soft tissue, without any bone mineral, the tissue composition for the pixel can be measured by calculating the relative attenuation by the fat and lean tissue of the two energy levels in the x-ray beam.

The Visceral Fat software algorithm combines direct measurements of fat and lean tissue with modeling information about the distribution of fat in the android region.

A clinical trial was performed to compare dual-energy x-ray absorptiometry (DXA) estimated visceral fat adipose tissue (VAT) with the accepted research standard for VAT imaging, computed tomography (CT), using the Advantage Windows Tissue Volume option (K963345).

COMPARISON WITH PREDICATE DEVICES:

The GE Lunar Visceral Fat Software option for GE Lunar DEXA Bone Densitometers is of comparable type and substantially equivalent to the GE Lunar Body Composition Software option (K071570). It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction and materials, and has similar intended uses as the GE Lunar Body Composition Software option.

ADVERSE EFFECTS ON HEALTH:

The device has been evaluated for electrical, mechanical, and radiation safety, and conforms to applicable medical device safety standards, as confirmed by a Nationally Recognized Test Laboratory.

The potential hazards of electrical and mechanical are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards.
- Compliance to applicable CDRH 21 CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820.

CONCLUSION:

The GE Lunar Visceral Fat Software is an extension of the currently cleared GE Lunar Body Composition Software (K071570). It does not result in any new potential safety risks, has the same technological characteristics, and performs as well as the devices currently on the market.

After analyzing performance testing on the bench and in a clinical trial it is the conclusion of GE Healthcare that the GE Lunar Visceral Fat Software is substantially equivalent to other marketed devices with similar indications for use and meeting the same standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 10 2011

Mr. Chris Paulik
Regulatory Affairs Leader
GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
Doing business as GE Medical Systems Lunar
3030 Ohmeda Drive
MADISON WI 53718

Re: K103730
Trade/Device Name: GE Lunar Visceral Fat Software
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: December 20, 2010
Received: December 21, 2010

Dear Mr. Paulik:

This letter corrects our substantially equivalent letter of May 6, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if Known):

Device Name: GE Lunar Visceral Fat Software

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The GE Lunar Visceral Fat Software option used on GE Lunar DEXA bone densitometer total body scans estimates the visceral adipose tissue (visceral fat) content within the android region in a male or female population between the age of 18 and 90 with a BMI between 18.5 and 40, excluding pregnant women. The content that is estimated is the Visceral Fat Mass and Visceral Fat Volume. The values can be displayed in user defined statistical formats and trends.

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Prescription Use_ X ___ AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

5/6/11

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103730